HOUSE BILL No. 1703

DIGEST OF INTRODUCED BILL

Citations Affected: IC 12-15.

Synopsis: Medicaid preferred drug list. Allows the office of Medicaid policy and planning to add a drug that has been approved by the federal Food and Drug Administration to the preferred drug list without prior approval from the drug utilization review board (board). Permits the board to add a drug that has been approved by the federal Food and Drug Administration to the preferred drug list. (Current law allows: (1) the office to add only new single source drugs to the preferred drug list without prior approval of the board; and (2) the board to add only new single source drugs to the preferred drug list.) Makes cross references.

Effective: July 1, 2003.

Brown C

January 21, 2003, read first time and referred to Committee on Public Health.

Introduced

First Regular Session 113th General Assembly (2003)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2002 Regular or Special Session of the General Assembly.

HOUSE BILL No. 1703

A BILL FOR AN ACT to amend the Indiana Code concerning Medicaid.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 12-15-35-28, AS AMENDED BY P.L.107-2002, SECTION 17, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 28. (a) The board has the following duties:

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in

retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review

with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

(11) The research, development, and approval of a preferred drug list for:

(A) Medicaid's fee for service program;

(B) Medicaid's primary care case management program; and

(C) the primary care case management component of the children's health insurance program under IC 12-17.6;

in consultation with the therapeutics committee.

(12) The approval of the review and maintenance of the preferred drug list at least two (2) times per year.

(13) The preparation and submission of a report concerning the preferred drug list at least two (2) times per year to the select joint commission on Medicaid oversight established by IC 2-5-26-3.

(14) The collection of data reflecting prescribing patterns related to treatment of children diagnosed with attention deficit disorder or attention deficit hyperactivity disorder.

(b) The board shall use the clinical expertise of the therapeutics committee in developing a preferred drug list. The board shall also consider expert testimony in the development of a preferred drug list.

(c) In researching and developing a preferred drug list under subsection (a)(11), the board shall do the following:

(1) Use literature abstracting technology.

(2) Use commonly accepted guidance principles of disease management.

(3) Develop therapeutic classifications for the preferred drug list.

(4) Give primary consideration to the clinical efficacy or appropriateness of a particular drug in treating a specific medical condition.

(5) Include in any cost effectiveness considerations the cost implications of other components of the state's Medicaid program and other state funded programs.

(d) Prior authorization is required for coverage under a program described in subsection (a)(11) of a drug that is not included on the preferred drug list.

(e) The board shall determine whether to include a single source covered outpatient drug that is newly approved by the federal Food and Drug Administration on the preferred drug list not later than sixty (60) days after the date of the drug's approval. However, if the board determines that there is inadequate information about the drug

available to the board to make a determination, the board may have an additional sixty (60) days to make a determination from the date that the board receives adequate information to perform the board's review. Prior authorization may not be automatically required for a single source drug that is newly approved by the federal Food and Drug Administration and that is:

(1) in a therapeutic classification:

(A) that has not been reviewed by the board; and

(B) for which prior authorization is not required; or

(2) the sole drug in a new therapeutic classification that has not been reviewed by the board.

(f) The board may not exclude a drug from the preferred drug list based solely on price.

(g) The following requirements apply to a preferred drug list developed under subsection (a)(11):

(1) **Except as provided by IC 12-15-35.5-3(b),** the office or the board may require prior authorization for a drug that is included on the preferred drug list under the following circumstances:

(A) To override a prospective drug utilization review alert.

(B) To permit reimbursement for a medically necessary brand name drug that is subject to generic substitution under IC 16-42-22-10.

(C) To prevent fraud, abuse, waste, overutilization, or inappropriate utilization.

(D) To permit implementation of a disease management program.

(E) To implement other initiatives permitted by state or federal law.

(2) All drugs described in IC 12-15-35.5-3(b) must be included on the preferred drug list.

(3) The office may add a ~~new single source~~ drug that has been approved by the federal Food and Drug Administration to the preferred drug list without prior approval from the board.

(4) The board may add a ~~new single source~~ drug that has been approved by the federal Food and Drug Administration to the preferred drug list.

(h) At least two (2) times each year, the board shall provide a report to the select joint commission on Medicaid oversight established by IC 2-5-26-3. The report must contain the following information:

(1) The cost of administering the preferred drug list.

(2) Any increase in Medicaid physician, laboratory, or hospital costs or in other state funded programs as a result of the preferred

drug list.

(3) The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.

(4) The number of times prior authorization was requested, and the number of times prior authorization was:

(A) approved; and

(B) disapproved.

(i) The board shall provide the first report required under subsection (h) not later than six (6) months after the board submits an initial preferred drug list to the office.

SECTION 2. IC 12-15-35-28.7, AS ADDED BY P.L.107-2002, SECTION 19, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 28.7. (a) The board shall submit the initial approved preferred drug list to the office not later than August 1, 2002.

(b) Except as permitted under subsection (g), the office may not further restrict the status of a drug in the Medicaid program or the children's health insurance program until the board reviews a therapeutic classification and the office implements the therapeutic classification on the preferred drug list.

(c) The office shall provide advance notice to providers of the contents of the preferred drug list submitted by the board under subsection (a).

(d) Notwithstanding IC 12-15-13-6, the office shall implement any change in the preferred drug list not later than thirty (30) days after the date the board submits the amended list to the office.

(e) **Except as provided by section 28(g)(3) of this chapter,** the office may not implement a preferred drug list or an amendment to the preferred drug list that has not been approved by the board.

(f) The office may not require prior authorization for a drug that is excluded from the preferred drug list unless the board has made the determinations required under section 35 of this chapter.

(g) The office may adopt rules under IC 4-22-2 necessary to carry out this chapter.

SECTION 3. IC 12-15-35.5-2.5, AS ADDED BY P.L.107-2002, SECTION 23, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2003]: Sec. 2.5. As used in this chapter, "unrestricted access" means the ability of a recipient to obtain a prescribed drug without being subject to limits or preferences imposed by the office or the board for the purpose of cost savings except **to address situations described in IC 12-15-35-28(a)(8)(A) through (K) and** as provided under ~~IC 12-15-35-8 and~~ section 7 of this chapter.